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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,803	12/14/2005	Daniel T. Green	022354-000310US	7164

20350 7590 10/24/2007

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EXAMINER	
AUDET, MAURY A	

ART UNIT	PAPER NUMBER
1654	

MAIL DATE	DELIVERY MODE
10/24/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Suppl. **Notice of Allowability**	Application No. 10/540,803	Applicant(s) GREEN ET AL.	
	Examiner Maury Audet	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *7/23/07*.

2. ☒ The allowed claim(s) is/are *5,6,8,10,12-13,18 and 19*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date 05/07
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

SUPPLEMENTAL EXAMINER'S AMENDMENT

The present Supplemental Examiner's Amendment is being sent to acknowledge that claim 13 was allowed, but inadvertently left off both Form 326 and below, as allowed. The correction is herein duly noted. As well as send the initialed/dated/signed Form 1449 for the IDS submitted 05/07, submitted just prior to the Advisory Action that was sent by the Office.

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was approved by Ted Apple, Applicant's Representative, during a telephone conversation held on 8/30/07.

IN THE CLAIMS

Claim 5 is replaced in its entirety to now claim:

5. (Currently Amended) A method of reducing the risk of insulin-induced hypoglycemia in a diabetes patient who is being treated with insulin, which method comprises administering to the patient an amount of glucagon that results in a plasma glucagon level in the range achieved by intravenous infusion of glucagon at a rate that is not less than 0.10 ng/kg/min and not more than 5.00 ng/kg/min,

wherein glucagon is administered daily as part of a diabetes treatment regimen, and

wherein said patient is not suffering hypoglycemic symptoms and has a blood glucose level of from 70-110 mg/dL when said glucagon is administered.

In claim 18, line 1, the phrase "basal replacement dose" has been deleted and term --administration-- inserted.

Claims 9 and 20-25 have been cancelled without prejudice.

Reasons for Allowance

The following is an examiner's statement of reasons for allowance:

The prior art of record does not reasonably teach or suggest the presently claimed method, wherein a proactive daily basal amount of glucagons, while is administered alongside insulin administration to offset the decrease in glucose levels stimulated by the effect of insulin and reduce the risk of hypoglycemic states common in diabetics, as a result of insulin administration. The benefits daily basal glucagon administration in diabetics are shown the IDS submission of 8/28/07, in the slides bearing test data to this effect, which Applicant recently presented before the ADA (American Diabetic Association).

Houlbert et al. (IDS, 5/2/07; "Continuous Subcutaneous Infusion of Glucagon by Portable Pump in Non Beta Cell Tumor Hypoglycemia," Diabete & Metab. 11 (2):125-7, April 1985)) is now deemed the closest prior art of record to the present invention, albeit non-analogous art, since not utilized alongside insulin or in diabetes therapy. Houlbert et al. is drawn to daily (nightly) administration of low dose glucagon to reduce the risk of hypoglycemia in a patient suffering from non-beta cell tumor hypoglycemia, in both continuous/low dose glucagons

administration was found to be successful in reducing the risk of hypoglycemia. However, the '85 reference does not provide the teaching/suggestion and thus motivation, alone or in combination with secondary references from analogous insulin/diabetic therapy art - to arrive at the present invention of a proactive daily basal glucagon administration alongside insulin to reduce the risk of hypoglycemia in diabetic therapy. The art of record can be summarized as reactive, rather than proactive. In that glucagon is administered, even via pump, only when near or at hypoglycemic levels have been detected in the body; rather than administering low levels to reduce the risk of hypoglycemic levels even occurring.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Claims 5-6, 8, 10, 12-13, and 18-19 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 571-272-0960. The examiner can normally be reached on M-Th. 7AM-5:30PM (10 Hrs.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MA, 10/23/2007

Cecilia J. Tsang
Supervisory Patent Examiner
Technology Center 1600